REMARKS/ARGUMENTS

Claims 1, 5-7, 9, 11-14, 16-19 and 105-112 are active in this case.

Support for the amendments to Claims 13, 17 and 19 find support in independent claim 1.

Support for intravenous administration in Claims 105-112 is found in paragraph 109 of the specification as originally filed.

No new matter is added.

The rejection of Claims 1, 9, 18 and 106-108 under 35 USC 102(b) in view of Heard is not tenable because (A) Heard does not explicitly describe treating traumatic brain injury (TBI) but certain types of infections; (B) Heard does not inherently describe treating TBI; and (C) Heard does not describe intravenous administration as set forth in Claim 105. Each of these points are expanded on the following discussion.

(A) Heard does not explicitly describe treating traumatic brain injury (TBI) but certain types of infections

Heard is cited in the Action allegedly because it "teaches a method for the treatment of TBI comprising administering recombinant human GCSF" (page 5, paragraph 13 of the Action). This is incorrect.

Heard merely presents a study on the use of GCSF for the prophylactic treatment of "nosocomial infections in intubated patients with acute TBI or intracerebral hemorrhage" (pp. 749, 1st col. 2nd ¶) but does not describe treating TBI in the patients.

(B) Heard does not inherently describe treating TBI

As there can be no mistake that Heard is treating nosocomial infections, the rejection must be based on the presumption that as Heard mentions that some of the intubated patients also have TBI, the administration of GCSF inherently treats the intubated patient that may

also have TBI. However, the Examiner has provided no proof of this. As noted by the court in *In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323 (CCPA 1981), the mere fact that a certain thing may result from a given set of circumstances is not sufficient to prove inherency. Inherency may not be established by probabilities or possibilities. Something that is inherent must inevitably be the result each and every time.

It is by now well settled that the burden of establishing a *prima facie* case of anticipation resides with the Patent and Trademark Office. *In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984), quoting *In re Warner*, 379 F.2d 1011, 1016, 154 USPQ 173, 177 (CCPA 1967).

As noted by the Board of Patent Appeals and Interferences in *Ex parte Skinner*, 2 USPQ2d 1788, before an Examiner can switch the burden of proof of showing non-inherency to the applicant, the Examiner must provide some evidence or scientific reasoning to establish the reasonableness of the Examiner's belief that the functional limitation is an inherent characteristic of the prior art. In this case, the Examiner has provided no such evidence.

Heard does not present a beneficial effect on the TBI symptoms nor even discuss such an effect. All of the targeted patients of this study were intubated but not necessarily due to a prior TBI. Indeed, it is equally possible that the patients treated in this study may have had intracerebral hemorrhage (NOT TBI). Heard is silent about the ratio of TBI patients in this study and as one third of the patients were treated with placebo it is also equally possible that there were no TBI patients among the GCSF treated ones (table 1).

Heard does not describe what patients (having intracerebral hemorrhage or TBI) received what (GCSF or placebo), there is nothing more than a possibility that Heard administered GCSF to a TBI patient --noting at least a similar possibility that no TBI patient received GCSF. As inherency cannot be established by probabilities or possibilities but rather

must inevitably be the result each and every time and Heard's disclosure does not do that, the claims presented here cannot be anticipated by Heard.

(C) Heard does not describe intravenous administration as set forth in Claim 105

Heard describes only subcutaneous administration of GCSF (Interventions in the Abstract and Materials and Methods on pp. 749, 2nd paragraph) which is the usual mode of administration for a long term treatment such as the infection prophylaxis of this study. Intravenous administration as defined in Claims 105-112 is not described

Withdrawal of the rejection based on Heard is requested.

To the obviousness rejections citing primarily Heard with Brines, Deleuze, Morita-Fujimura, Curran and Goa, and/or MacVitte, these rejections also fail because they are relied upon for features in various dependent claims (see pp. 7-13 of the Action) but do not (A) explicitly describe treating traumatic brain injury (TBI); (B) inherently describe treating TBI; and (C) describe intravenous administration as set forth in Claim 105. Further, Heard would not have been modified to treat the underlying condition of TBI because Heard is silent about such effects.

Withdrawal of the rejections under 35 USC 103 is requested.

The rejection under 35 USC 112, second paragraph is traversed.

The term hemodynamic active is neither novel nor indefinite. Indeed, hemodynamic is a well-known term in the field and generally deals with controlling the circulation of blood through the body (see, e.g., attached print out from the International Hemodynamic Society, www.hemodynamicsociety.org). Whether a compound does this or not can easily be ascertained by one in the field. Thus, Claim 11 sets out and circumscribes a particular subject matter with a reasonable degree of clarity and particularity.

In Claim 13, the term facilitates has been modified so as to clarify what is being claimed. That is the agent "facilitates" passage of the GCSF or its derivatives as now defined in Claim 13 to pass through the blood-brain barrier. The term facilitates is a well-defined term, e.g., as defined by dictionary.com it is "to make easier or less difficult; help forward (an action, a process, etc.)" Thus, the agent here makes it easier or less difficult for GCSF to pass through the blood brain barrier, a notoriously well-known barrier for directed therapy in the brain.

Claims 17 and 19 have been amended to clarify what hematopoietic factor is referenced.

Regarding Claim 18, the only instance of mammal in Claim 1 is that which is being treated. "Mammalian" is used to modify the GCSF. So no lack of clarity exists. Nonetheless, so this case is not held up on this misunderstanding, what "mammal" in claim 1 is referenced in Claim 18 has been amended.

Claim 105 no longer includes the phrase "via stimulation of adult neuronal stem cells."

Withdrawal of the rejection is requested.

To the provisional obviousness double patenting rejection in view of claims 1-5, 9-22 and 52-53 of co-pending application no. 10/880,101. The rejection is premised on a list of diseases being treated that are not, at least in the terms set forth on page 14 of the Action, actually what is defined in the claims here nor the claims in the '101 application.

The claims here are for treating traumatic brain injury (TBI) whereas the pending claims of the 10/880,101 are for treating peripheral neuropathy. Treating one condition does not necessarily result in treating the other condition and vice versa nor would it be obvious to do so.

Withdrawal of the rejection is requested.

A Notice of Allowance is also requested.

Respectfully submitted,

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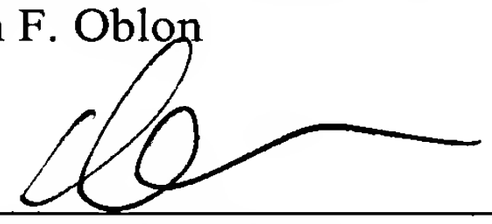

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